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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,703	07/22/2003	Ronald Legge	4359-A1	7048
29370	7590	10/16/2006	EXAMINER	
ROBERT A. PARSONS 4000 N. CENTRAL AVENUE, SUITE 1220 PHOENIX, AZ 85012			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER

1743

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/624,703	Applicant(s) LEGGE ET AL.	
	Examiner Lyle A. Alexander	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 4-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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In response to the 7/28/06 amendments a new search was performed and new pertinent references were discovered for the first time that are applied below in new grounds of rejections.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 and 4-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-2 and 4-6 are to an apparatus that includes the finger nail of the user.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Apparatus claims 1-2 and 4-6 are not clear what apparatus structure is intended. The only structures claimed are a **“a layer including substance chemically reactive to a suspected drug”** and a **“finger nail”**. The **“finger nail”** is part of the human body and non-statutory subject matter. The only structure available for examination is the layer.

Claims 4-7,10,12,13,15 and 16 all reference "finger" which should be changed to --finger nail--. It is not clear how the polish/decal could be applied to the finger rather than the finger nail as taught in the specification.

Claim 4 does not appear to further limit claim 1. Independent claim 1 is directed to a chemically reactive substance. Claim 4 stated the "layer" is in the form of a decal. As presently claimed, the chemically reactive substance is not in the decal. Clarification could be achieved by claiming the decal is coated by the chemically reactive substance.

Claim 10 does not appear to further limit claim 7. Independent claim 7 is directed to a method of coating a finger nail whereas claim 10 is directed to application of a decal which does not further limit claim 7. Clarification could be achieved by making claim 10 an independent claim.

Claims 4 and 10 are also confusing as to the application of the finger nail decal. The claims should specify the decal has been coated with the reagent and the decal is attached to the finger nail. Applicants' should also better describe what method steps are performed to attach the decal to the finger nail to define over Craig et al.(e.g. the test strips of Craig et al. were broadly read on the claimed decals in the 4/26/06 Office action). Applicants' should consult the original specification to specify how the decal is attached to the finger nail,

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 4-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Craig et al.

See the appropriate paragraph of the 4/26/06 Office action.

Claim 1 is directed to a chemically reactive substance that can be applied as a layer. Craig et al. clearly teach a chemically reactive substance that is applied as a layer. The claimed application of the layer to a "finger nail" has been read as a method of intended use and is of no patentable moment with respect to the claimed apparatus(e.g. the "chemically reactive substance"). Again, as stated in the 4/26/06, in the absence of better describing what composition is intended by "finger nail polish", the Office maintains Craig et al. teach a chemically reactive substance that has the capability of being used as a finger nail polish (e.g. the claimed apparatus must have the capability of performing the method to be clearly anticipated). Also the limitations to coating on a plurality of fingers has been read as a method of intended use of the apparatus.

Claims 1-2 and 5-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Arndt (2003/0175224).

Arndt teaches in paragraphs [0006] through [0007] a method of applying a ninhydrin reagent containing a dye, that is compatible with the reagent, to finger nail of a human. The claimed "**substance chemically reactive to a suspected drug**" has

been read on the taught "*ninhydrin*". The claimed "**polish**" has been read on the taught "*dye that is compatible with the reagent*". The Office notes that it is notoriously well known in the art the taught ninhydrin is capable of a colorimetric reaction with a drug (e.g. see Konishi claim 4 cited below) and has been properly read on the claimed "**substance chemically reactive to a suspected drug**".

Allowable Subject Matter

Claims 13-16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art fails to teach or suggest a method of coating a "substance chemically reactive to a suspected drug" on a finger nail combined with the steps of "moistening the substance on the finger" and "observing any change of the layer on the finger nail, wherein the change indicates the presence of the suspected drug".

Response to Arguments

Applicant's arguments filed 7/28/06 have been fully considered and stated Applicants' have made the appropriate amendments to place the application in condition for allowance. The Office has reconsidered the previous indications of allowable subject matter in favor of the above rejections.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Konishi (20020006444) teaches in claim 4 ninhydrin used as a colorimetric indicator for a drug.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1743

